

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Mohamed Attawia, Hassan Serhan, Thomas M. DiMauro, Melissa Grace and

David Urbahns

Application No.:

10/714,594

Group Art Unit:

1649

Filed:

November 14, 2003

Examiner:

Steven H. Standley

Confirmation No.:

3230

Title:

AUTOLOGOUS TREATMENT OF DEGENERATED DISC WITH CELLS

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March 15, 2006

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

			Statement		

[]	under 37 CFR 1.129(a), or (First/Second submission after Final Rejection)
[X]	under 37 CFR 1.97(b), or (Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).
[]	under 37 CFR 1.97(c) together with either:
	[] a Statement under 37 CFR 1.97(e), as checked below, or
	[] a \$180.00 fee under 37 CFR 1.17(p), or (After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
[]	under 37 CFR 1.97(d) together with:
	[] a Statement under 37 CFR 1.97(e), as checked below, and
	[] a \$180.00 fee under 37 CFR 1.17(p), or (Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

[] under 37 CFR 1.97(i):

Applicant requests that the IDS and cited reference(s) be placed in the application file.

(Filed after payment of issue fee)

Staten	nent Un	ler 37 CFR 1.97(e)
[]	any co	em of information contained in this Information Disclosure Statement was first cited in nmunication from a foreign patent office in a counterpart foreign application not more ree months prior to the filing of this Information Disclosure Statement; or
[]	knowled in the	n of information contained in this Information Disclosure Statement was cited in a inication from a foreign patent office in a counterpart foreign application, and, to the edge of the undersigned, after making reasonable inquiry, no item of information contained information disclosure statement was known to any individual designated in 37 CFR more than three months prior to the filing of this Information Disclosure Statement.
Staten	nent Un	ler 37 CFR 1.704(d) (Patent Term Adjustment) Applies to original applications (other than design) filed on or after May 29, 2000
[]	comm was no	em of information contained in the Information Disclosure Statement was cited in a unication from a foreign patent office in a counterpart application and this communication treceived by any individual designated in § 1.56(c) more than thirty days prior to the of the Information Disclosure Statement.
[X]	Enclos	ed herewith is form PTO-1449:
	[X]	Copies of the cited references are enclosed. [AN-AM4 & AT5-AY13]
		[X] Copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
	[]	Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]
	[]	The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
	[]	The "concise explanation" requirement (non-English references) for reference(s) [under 37 CFR 1.98(a)(3) is satisfied by:
		[] the explanation provided on the attached sheet.

the explanation provided in the Specification.

the enclosed English language abstract.

submission of the enclosed International Search Report.

submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.

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[]		ant requests that the following numbel or apply the stamp "Non-Published IDS Rej		
Examiner's Initials				
		U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []
		U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []
-		U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []
		Examiner	Date	_
	[]	A copy of each above-cited app any application filed on or after Image File Wrapper (IFW) syst	r June 30, 2003, which has b	een scanned into the PTO's
	[]	A copy of each above-cited app those entered in prior application 35 U.S.C. 120 is claimed.		nt claims, is enclosed, except], to which priority under
		r is requested to return a copy of re considered with the next office		plications indicating which
It is re	quested	that the information disclosed h	nerein be made of record in the	his application.
Metho	d of pay	yment:		
[]		ck for the fee noted above is enc panying Reply. A copy of this S		cluded in the check with the
[]	Please enclos	charge Deposit Account 08-038 ed.	30 in the amount of \$[]. A copy of this Statement is
[X]	Please	charge any deficiency in fees as	nd credit any overpayment to	Deposit Account 08-0380.
		1	Respectfully submitted,	
		1	HAMILTON, BROOK, SMI	TH & REYNOLDS, P.C.
			Christine M. Doe Registration No.: 58,073 Telephone: (978) 341-0036 Facsimile: (978) 341-0136	le De
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SUPPLEMENTAL ENFORMATION DISCLOSURE STATEMENT IN AN APPLICATION

March 15, 2006

(Use several sheets if necessary)

			Sheet I of I
ATTORNEY DOCKET NO. 3518.1012-005	1	LICATION NO. 714,594	
FIRST NAMED INVENTOR Mohamed Attawia		FILING DATE November	14, 2003
EXAMINER Standley, Steven H.	CONFI 3230	RMATION NO.	GROUP 1649

- VE HAY		U.S	S. PATENT DOCUMENTS	
EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	АН	4,427,649	01-24-1984	Dingle, et al.
	AI	5,095,037	03-10-1992	Iwamitsu, et al.
	AJ	5,116,964	05-26-1992	Capon, et al.
	AK	5,225,538	07-06-1993	Capon, et al.
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_	AC2	5,368,841	11-29-1994	Trauner, et al.
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	AB3	6,294,170	09-25-2001	Boone, et al.
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	AF3	6,590,081	07-08-2003	Zhang
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	AI3	US 2001/0006948 A1	07-05-2001	Kang, et al.
	AJ3	US 2001/0016195 A1	07-05-2001	Tobinick

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PTO-1449 REPRODUCED SUPPLEMENTAL	ATTORNEY DOCKET NO. 3518.1012-005		APPLICATION NO. 10/714,594		
INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION	FIRST NAMED INVENTOR Mohamed Attawia		FILING DATE November 14, 2003		
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	AK3	US 2001/0026801 A1	10-04-2001	Tobinick				
	AA4	US 2002/0010471 A1	01-24-2002	Wironen, et al.				
	AB4	US 2002/0026244 A1	02-28-2002	Trieu				
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,	AF4	US 2003/0007972 A1	01-09-2003	Tobinick				
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	AK4	US 2002/0169162	11-14-2002	Smith, et al.				

EXAMINER	DATE CONSIDERED

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION

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	ATTORNEY DOCKET NO. 3518.1012-005		PLICATION NO. /714,594	
	FIRST NAMED INVENTOR Mohamed Attawia		FILING DATE November	14, 2003
	EXAMINER Standley, Steven H.	CONF 323	IRMATION NO.	GROUP 1649

	F	OREIGN PATENT D	OCUMENTS	
	DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	TRANSLATION YES NO
AN	EP 0 218868 A2	04-22-1987	New York Blood Center, Inc.	
 AO	EP 0 288 088 B1	10-26-1988	Teijin Limited	
AP	EP 0 438234 A1	07-24-1991	Kita	
AQ	EP 0 950417 A2	02-15-1999	Pfizer Products, Inc.	
AL2	EP 1 133995 A2	09-19-2001	Synergen, Inc.	
AM2	EP 1 153607 A2	11-14-2001	Dunn	
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AO2	WO 02/057240 A1	07-25-2002	Ortho McNeil Pharmaceutical, Inc.	
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AL3	WO 91/02078 A1	02-21-1991	Peptide Technology LTD	
AM3	WO 92/07076 A1	04-30-1992	The Charring Cross Sunley Research Centre	
AN3	WO 92/16553 A1	10-01-1992	New York University and Centocor, Inc.	
AO3	WO 93/16099 A2	08-19-1993	Biopharm Gesellschaft Zur Biotechnologischen Entwicklung Von Pharmaka MBH	
AP3	WO 97/28828 A1	08-14-1997	Amgen Boulder, Inc.	
AQ3	Intentionally Omitted			
AL4	WO 98/24477 A1	06-11-1998	Amgen, Inc.	
AM4	WO 99/45923 A1	09-16-1999	Merck & Co., Inc.	
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ATTORNEY DOCKET NO. 3518.1012-005	LICATION NO. 714,594
FIRST NAMED INVENTOR	FILING DATE

EXAMINER CONFIRMATION NO. GROUP Standley, Steven H. 1649 3230

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AT5	Abstracts of the N. American Spine Society 17 Annual Meeting, Montreal, Canada, October 29 through November 2, 2002, <i>The Spine Journal</i> , 2(5Suppl.). 49S-50S (2002).
AU5	Allai, F., et al., "Increase in Bone Mineral Density of Patients with Spondyloarthropathy Treated With Anti-Tumor Necrosis Factor α," Ann. Rheum. Dis., 62:347-349 (2003).
AV5	Andonopoulos, A.P., et al., "Intra-articular Anti-Tumor Necrosis Factor α Antibody in Recalcitrant Arthritis of Behçet's Disease," Clinical and Experimental Rheumatology 21(4 Suppl 30): S-57-S58 (July-August 2003).
AW5	Aoki, Y., et al., "Local Application of Disc-Related Cytokines on Spinal Nerve Roots," Spine, 27(15): 1614-1617 (2002).
AX5	Ariga, K., et al., "Mechanical Stress-Induced Apoptosis of Endplate Chondrocytes in Organ-Cultured Mouse Intervertebral Discs," Spine, 28(14): 1528-1533 (2003).
AY5	Ashkenazi, A., et al., "Protection Against Endotoxic Shock by a Tumor Necrosis Factor Receptor Immunoadhesin," Proc. Natl. Acad. Sci. USA, 88, pp. 10535-10539.
AZ5	Baker, D., et al., "Control Established Experimental Allergic Encephalomyelitis by Inhibition of Tumor Necrosis Factor (TNF) Activity Within the Central Nervous System using Monoclonal Antibodies and TNF Receptor-Immunoglobulin Fusion Proteins," Eur. J. Immunol., 24:2040-2048 (1994)
AR6	Biskobing, D. M., "Novel Therapies for Osteoporosis," Expert Opinion Invest. Drugs, 12(4): 611-621 (2003).
AS6	Bokarewa, M., et al., "Local Infusion of Infliximab for the Treatment of Acute Joint Inflammation," Ann. Rheum. Dis., downloaded from ard.bmjjournals.com on 30 November 2005, www.annrheumdis.com 62:783-784 (2003).
AT6	Boehm, et al., "New Inhibitors of p38 Kinase," Exp. Opin, Ther. Patents, 10(1):25-37 (2000).
AU6	Braun, J. and Sieper J., "Overview of The Use of The Anti-TNF Agent Infliximab in Chronic Inflammator, Diseases," <i>Expert Opin. Biol. Ther.</i> 3(1):141-168 (2003).
AV6	Braun, J., et al., "Anti-Tumour Necrosis Factor α Therapy for Ankylosing Spondylitis: International Experience," Ann. Rheum. Dis., 61(Supp. III):iii51-iii60 (2002).

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FIRST NAMED INVENTOR Mohamed Attawia		FILING DATE November 14, 2003

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	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
AW6	Bringman, T.S. et al., "Monoclonal Antibodies to Human Tumor Necrosis Factors Alpha and Beta: Application for Affinity Purification, Immunoassays, and as Structural Probes," <i>Hybridoma</i> , 6(5):489-507 (1987).
AX6	Brown, K., et al., "Gelatin/Chondroitin 6-Sulfate Microspheres for the Delivery of Therapeutic Proteins to the Joint," Arthritis. & Rheum., 41(12):2185-2195 (1998).
AY6	Burke, J.G., et al., "Intervertebral Discs Which Cause Low Back Pain Secrete High Levels of Proinflammatory Mediators," J. Bone Joint Surg. [Br] 84-B, 196-201 (2001).
AZ6	Butler, D. et al., "TNF Receptor Fusion Proteins are Effective Inhibitors of TNF-Mediated Cytotoxicity of Human KYM-1D4 Rhabdomyosarcoma Cells," Cytokine, 6(6):616-623 (1994).
AR7	Capon, D. et al. "Designing CD4 Immunoadhesins for AIDS Therapy," Nature, 337:525-531 (1989).
AS7	Cardone, D. A., et al., "Diagnostic and Therapeutic Injection of the Hip and Knee," Am. Fam. Physician, 67(10): 2147-2152 (2003).
AT7	Chae, H.J. et al., "The p38 Mitogen-Activated Protein Kinase Pathway Regulates Interleukin-6 Synthesis in Response to Tumor Necrosis Factor in Osteoblasts," Bone, 28(1): 45-53 (2001).
AU7	Cirillo et al., "The Non-Diaryl Heterocycle Classes of p38 MAP Kinase Inhibitors," Current Topics in Medicinal Chemistry, 2: 1021-1035 (2002).
AV7	Conti, F., et al., "Successful Treatment With Intraarticular Infliximab for Resistant Knee Monarthritis in a Patient With Spondylarthropathy," Arthritis & Rheumatism, 52(4): 1224-1226 (2005).
AW7	Corcoran, A.E. et al., "Characterization of Ligand Binding by the Human p55 Tumour-Necrosis-Factor Receptor," Eur. J. Biochem., 223:831-840 (1994).
AX7	Crandall, C., "Combination Treatment of Osteoporosis: A Clinical Review," J. of Women's Health & Gender-Based Medicine, 11(3):211-224 (2002).
AY7	Dayer, J.M., "The Pivotal Role of Interleukin-1 in the Clinical Manifestations of Rheumatoid Arthritis," Rheumatology, Oxford University Press, London, GB, 42(Suppl 2):ii03-ii10 (2003).
AZ7	DeSantis, A. and Buchman, A., "Current and Emerging Therapies in Osteoporosis," <i>Expert Opin. Pharmacother.</i> , 3(7):835-843 (2002).

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AR8	Diwan, A. D., et al., "Current Concepts in Intervertebral Disk Restoration," Tissue Engineering in Orthopedic Surgery, 31(3):453-464 (2000).
AS8	Engelmann, H. et al., "Two Tumor Necrosis Factor-Binding Proteins Purified From Human Urine," J. Biol. Chem., 265(3):1531-1536 (1990).
AT8	Ezra, A., and Golomb, G., "Administration Routes and Delivery Systems of Bisphosphonates for the Treatment of Bone Resorption," <i>Adv. Drug Del. Rev.</i> , 42:175-195 (2000).
AU8	Fendly et al., "Murine Monoclonal Antibodies Defining Neutralizing Epitopes on Tumor Necrosis Factor," <i>Hybridoma</i> , 6:359-370 (1987).
AV8	Gabay, C., "IL-1 Trap," Curr. Opin. Invest. Drugs, Curr. Drugs, London, GB, 4(5):593-597 (2003).
AW8	Goodman, S. et al., "Effects of Local Infusion of TGFβ on Bone Ingrowth in Rabbit Chambers," J. Biomed. Mat. Res. (Appl Biomater), 53:475-479 (2000).
AX8	Gordon, J. L., et al., "Metalloproteinase Inhibitors as Therapeutics," Clin. Exp. Rheumatol., 11(Suppl. 8): S91-S94 (1993).
AY8	Goupille, P., et al., "Matrix Metalloproteinases The Clue to Intervertebral Disc Degeneration?," Spine, 23(14): 1612-1626 (1998).
AZ8	Hirai, M. et al., "Production and Characterization of Monoclonal Antibodies to Human Tumor Necrosis Factor," J. Immunol. Meth., 96:57-62 (1987).
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АТ9	Johnson, W.H., et al., "Collagenase Inhibitors: Their Design and Potential Therapeutic Use," J. Enzyme Inhib., 2:1-22 (1987).
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AX9	Kimble, R.B. et al., "The Functional Block of TNF but Not of IL-6 Prevents Bone Loss in Ovariectomiz Mice," J. Bone Min. Res., 12(6):935-941 (1997).
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AS10	Lee, et al., "Inhibition of p38 MAP Kinase as a Therapeutic Strategy," Immunopharmacology, 47: 185-2 (2000).
AT10	Lehman, T. J. A., et al., "Thalidomide Therapy for Recalcitrant Systemic Onset Juvenile Rheumatoid Arthritis," J. Pediatrics, 140(1):125-127 (2002).
AU10	Lesslauer, W., et al., "Recombinant Soluble Tumor Necrosis Factor Receptor Proteins Protect Mice from Lipopolysaccharide-Induced Lethality," Eur. J. Immunol., 21:2883-2886 (1991).
AV10	Liang, CM., et al., "Production and Characterization of Monoclonal Antibodies Against Recombinant Human Tumor Necrosis Factor/Cachectin," Biochem. Biophys. Res. Comm. 137(2):847-854 (1986).
AW10	Loetscher, H. et al., "Molecular Cloning and Expression of the Human 55 kd Tumor Necrosis Factor Receptor," Cell, 61:351-359 (1990).
AX10	Maeda, S. and Kokubun, S., "Changes With Age in Proteoglycan Synthesis in Cells Cultured <i>In Vitro</i> From the Inner and Outer Rabbit Annulus Fibrosus," <i>Spine</i> , 25(2):166-169 (2000).

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AY10	Meager, A. et al., "Preparation and Characterization of Monoclonal Antibodies Directed Against Antigenic Determinants of Recombinant Human Tumour Necrosis Factor (rTNF)," <i>Hybridoma</i> , 6(3):305-311 (1987).
AZ10	Möller, A. et al., "Monoclonal Antibodies to Human Tumor Necrosis Factor α: In Vitro and In Vivo Application," Cytokine 2(3):162-169 (1990).
AR11	Molloy, T., et al., "The Roles of Growth Factors in Tendon and Ligament Healing," Sports Med., 33(5): pp.381-394 (2003).
AS11	Müller, R. "Determination of Affinity and Specificity of Anti-Hapten Antibodies by Competitive Radioimmunoassay," <i>Meth. Enzymol., 92</i> :589-601 (1983).
AT11	Nakamura, K. et al., "Local Application of Basic Fibroblast Growth Factor into the Bone Increases Bone Mass at the Applied Site in Rabbits," Arch. Orthop. Trauma Surg., 115(6):344-346 (1996).
AUI1	Nakamura, K. et al., "Stimulation of Endosteal Bone Formation by Local Intraosseous Application of Basic Fibroblast Growth Factor in Rats," Rev. Rhum. [Engl. Ed.], 64(2):101-105 (1997).
AVII	Nikas, S. N., et al., "Treatment of Resistant Rheumatoid Arthritis by Intra-Articular Infliximab Injections: A Pilot Study," Ann. Rheum. Dis., downloaded from ard.bmjjournals.com on 2 November 2005, www.annrheumdis.com 63: 102-103 (2004).
AW11	Olmarker, K. and Rydevik, B., "Selective Inhibition of Tumor Necrosis Factor-\alpha Prevents Nucleus Pulposus-Induced Thrombus Formation, Intraneural Edema, and Reduction of Nerve Conduction Velocity," Spine, 26(8): 863-869 (2001).
AX11	Pacifici, R., "Editorial: Cytokines, Estrogen, and Postmenopausal Osteoporosis-The Second Decade," Endocrinology, 139(6):2659-2661 (1998).
AYII	Pargellis, C. et al., "Inhibition of p38 MAP Kinase by Utilizing a Novel Allosteric Binding Site," Nature Structural Biology, 9(4): 268-272 (2002).
AZ11	Pederson, A.W. et al., "Thermal Assembly of a Biomimetic Mineral/Collagen Composite," <i>Biomaterials</i> , 24:4881-4890 (2003).

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PTO-1449 REPRODUCED SUPPLEMENTAL			APPLICATION NO. 10/714,594	
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1	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
AR12	Peppel, K. et al. "A Tumor Necrosis Factor (TNF) Receptor-IgG Heavy Chain Chimeric Protein as a Bivalent Antagonist of TNF Activity," J. Exp. Med., 174:1483-1489 (1991).
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EXAMINER	DATE CONSIDERED

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION March 15, 2006 (Use several sheets if necessary)			APPLICATION NO. 10/714,594	
	FIRST NAMED INVENTOR Mohamed Attawia		FILING DATE November 14, 2003	
	EXAMINER Standley, Steven H.	CONF. 3230	IRMATION NO.	GROUP 1649

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)	
AV13	Lane, N.E., et al., "Basic Fibroblast Growth Factor Forms New Trabeculae That Physically Connect with Pre-Existing Trabeculae, and this New Bone is Maintained With an Anti-Resorptive Agent and Enhanced With an Anabolic Agent in an Osteopenic Rat Model," Osteoporos Int, 14: 374-382 (2003).
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